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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,161	04/26/2001	Hidetaka Iwai	206580US0	6889

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EXAMINER	
YU, GINA C	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/842,161	IWAI ET AL.	
	Examiner	Art Unit	
	Gina C. Yu	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 4-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 2, 2004 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 is rejected as the claim is confusing. Claim 30 recites, "N-myristoyl-N-methyltaurine or N-stearoyl-N-methyltaurine". The claim appears to be incomplete. Claim 29 defines the surfactant as "a higher fatty acid amide sulfonic acid salt". Do applicants mean any specific type of salt of N-myristoyl-N-methyltaurine or N-stearoyl-N-methyltaurine?

As for claim 31, claim 1 defines that the surface active agents have dynamic surface tension less than 57 mN/m. Claim 31, which depends on claim 1, recites the surfactants other than as defined by claim 1, such as N-myristoyl-N-methyltaurine

sodium and cetyltrimethylammonium bromide, which have dynamic surface tension greater than 57 mN/m. See applicants' declaration p. 4. Claim 31 improperly depends on claim 1, or the scope of claim 31 is inconsistent with that of the base claim.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1, 2, 6-8, 10-21, 27-29, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu (English Translation of JP 63-126542 provided herewith).

Yu teaches transparent microemulsions containing hydrophilic ionic surfactants and oil components used for pharmaceuticals and cosmetics. See p. 2, lines 1 –17; p. 7, lines, 9-10. The reference teaches that the ratio of the nonionic surfactant to the oil ingredients in the invention may range from 1:05 to 1:10, and the emulsified particle size is 0.01-0.1 microns. See instant claims 1 and 3. See p. 4, lines 11-12. The application of the invention, such as liquid detergent, shampoo, hair tonic, etc, are disclosed in p. 7, lines 19-24. See instant claims 18 and 19.

Although Yu does not disclose any specific example formulation having the ratio of oil to hydrophilic surfactants that is greater than or equal to 10:1, the ratio of 10:1 is taught by the reference. Thus, one having ordinary skill in the art at the time of the invention was made would have had expected to successfully formulate a transparent microemulsion having such high oil to hydrophilic surfactant ratio.

The reference teaches anionic surfactants, cationic, amphiphilic surfactants, or mixture of thereof in p. 4, line 12 – p. 5, line 5. See instant claims 11-13. The reference

teaches N-acylglutamic acid salts and specifically teaches monosodium N-lauroyl glutamate, disodium N-stearoyl glutamate, nomosodium N-myristearyl-L-glutamate. See p. 4, fifth paragraph; instant claims 27. Sodium N-myristoyl-N-methyltaurine is taught. See p. 4, 4th par; instant claim 29. While the Yu reference does not teach dynamic surface tension of these surfactants, examiner notes that, since the prior art surfactants are the same compounds used in applicants' invention, and the dynamic surface tension is the same. For claim 31, the recited surfactants are disclosed in Example 31 and p. 4, 4th-5th par.

Examiner also notes that instant claims 1, 6, 7, and 15 are product-by-process claims. It is well settled in patent law that "if the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." See MPEP § 2113, quoting In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In this case, given the presumption of the obviousness of the product itself, the process of making thereof will not be given patentable weight. Nevertheless, the limitations are obvious view of the Yu reference teaching, in p. 7, lines 4- 8, to use a high pressure homogenizer or ultrasound emulsifying machine to produce strong shear stress of 400 atm or higher, or preferably of 600 atm or higher at a temperature below 50 °C. See instant claim 20. Examiner takes the position that employing the prior art equipments would obviously produce the shearing rate of the instant claims, unless proven otherwise.

2. Claims 4, 5, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu as applied to claims 1-3, 6-8, 10-21, 27-29, and 31 above, and further in view of Drapier et al. US 6121228 ("Drapier").

Yu further teaches that while liquid oils are preferred, oils in solid state may be used if they become liquid when mixed, suggesting mixing liquid and solid fatty components. See p. 5, line 6 – p. 6, last line. See also Tables for high alcohols, such as isostearyl alcohol, showing satisfactory transparent microemulsions. The Yu reference fails to teach an example of composition having both solid and liquid oil with specific viscosity.

Drapier teaches water-in-oil microemulsion liquid detergent having viscosity ranging from 6-300 milliPascal. See col. 4, lines 47 – 67; col.14, lines 17 - 26.

Given the teaching in Yu that the both liquid and solid oils may be used for variety of microemulsion applications such as liquid detergents, and the teaching that thickening agents may be added in the compositions, it would have been obvious to one having ordinary skill in the art to have expected successfully producing a product having desired viscosity by routine experimentations. The routineer who contemplates to formulate the liquid detergent according to Yu would have been motivated to adjust the viscosity as taught by Drapier.

3. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yu as applied to claims 1-3, 6-8, 10-21, 27-29, and 31 above, and further in view of Ansel (Pharmaceutical Dosage Forms and Drug Delivery Systems, 1990 5th ed.).

While Yu teaches that the HLB of the ionic surfactants should be hydrophilic since it is necessary to obtain oil-in-water type microemulsions, the reference fails to teach HLB of the surfactants.

Ansel teaches that surfactants having HLB of 8-18, and particularly HLB of 15-18 produce transparent microemulsion compositions. See Ansel, p. 244 col. 2, lines 9-13.

Given the general teaching of formulating o/w microemulsion compositions in Yu, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have been motivated to look to the prior arts such as Ansel for specific types and characteristics of the emulsifiers conventionally used in microemulsions.

4. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yu as applied to claims 1-3, 6-8, 10-21, 27-29, and 31 above, and further in view of Gers-Barlag et al. (US 5876702) ("Gers-Barlag").

The Yu reference fails to teach the surface tension of the oil components.

Gers-Barlag teaches that o/w microemulsions are obtained from oil components having surface tension of less than 30 mN/m. See col. 17, lines 15 – 30. The reference teaches that oils having a polarity between 10-20 mN/m are preferred. See also col. 17, lines 31 – 46 for specific types of oils.

Given the general teaching of formulating o/w microemulsion compositions in Yu, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have been motivated to look to the prior arts such as Gers-Barlag for specific types and characteristics of oils conventionally used in microemulsions.

5. Claims 23 and 25 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Yu as applied to claims 1-3, 6-8, 10-21, 27-29, and 31 above, and further in view of Diec et al. (US 6468551 B1) ("Diec").

Yu, discussed above, fails to teach using silicone oil in the microemulsion. Diec teaches cosmetic o/w microemulsions comprising hydrophilic o/w emulsifiers. See Example 22, comprising oil and the emulsifier in the weight ratio of greater than 10:1. See also col. 45, lines 31-39. The reference teaches that silicone oils are "advantageously" used in the invention, particularly mentioning polydimethylsiloxanes. See col. 25, lines 43 – 53. See instant claim 23 and 25.

Given the general teaching of formulating o/w microemulsion compositions in Yu, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have been motivated to look to the prior arts such as Diec for specific types oils conventionally used in microemulsions for cosmetic purposes. The skilled artisan would have expected to successfully produce a cosmetically advantageous composition.

6. Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu as applied to claims 1-3, 6-8, 10-21, 27-29, and 31 above, and further in view of Brunetta et al. (US 5562911) ("Brunetta").

Yu, discussed above, fails to teach fluoro-based oil.

Brunetta teaches that due to the formation of protective film on skin, the use of perfluoropolyether in cosmetic formulation is well known in the art. See col. 1, lines 15 – 56.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have substitute the oil in the Yu formulation with perfluoropolyether as motivated by Brunetta, because of the expectation of successfully producing a o/w microemulsion which forms protective film on the skin.

7. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yu as applied to claims 1-3, 6-8, 10-21, 27-29, and 31 above, and further in view of Shiojima et al. (US 6066316) ("Shiojima").

While the Yu reference teaches that nonionic surfactants are used to make microemulsions, the reference fails to teach polyoxyethylene alkyl ethers. See translation, p. 2, 3rd par.

Shiojima teaches a transparent oil-in-water hair cosmetic composition comprising POE behenyl ether. See col. 48, Test Example 22. The formula contains 32.5 % by weight of oil phase (Carnauba wax and liquid petrolatum) and 3.0 $ of POE-10 behenyl ether, meeting the weight ratio requirement of instant claim 1.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the invention of Yu by substituting the hydrophilic surfactants with POE-10 behenyl ether as motivated Shiojima because of an expectation of successfully producing cosmetic compositions with similar effects or hair cosmetic emulsion compositions.

Response to Arguments

Applicant's arguments with respect to claims 1, 2, and 4-31 have been considered but are unpersuasive.

Applicants' declaration filed on July 16, 2004 has been considered but is not persuasive. To rebut the presumption of obviousness, applicants must show unexpected results of the invention by clear and convincing evidence that commensurate with the scope of the claims. See MPEP § 716.02. Applicants indicate that the prior art surfactants used in the example formulation have dynamic surface tension slightly above 57 mN/m, and suggest that low transparency is obtained by using these surfactants in a particular formulation shown in declaration p. 2.

The claimed surfactants are taught to be useful to make microemulsion in the condition as recited by applicants (i.e., oil: surfactant ratio, particle size). While applicants assert that using surfactants with low dynamic surface tension produces better transparency, examiner is not convinced that such finding amounts to unexpected or surprising results that negates the prima facie obviousness in this case. Dynamic surface tension measures how rapidly the surface tension of water (surface tension 56.7mN/m) is reduced. Examiner views that it is within the skill of the art that the surfactants with lower dynamic surface tension than water would better reduce the surface tension of water. Nevertheless, the rejection is made in view of the strong teachings of the reference that the claimed surfactants are well known in microemulsion art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-0635.

The examiner can normally be reached on Monday through Friday, from 8:30 AM until 6:00 PM..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gina Yu
Patent Examiner

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER